

REMARKS

The applicant appreciates the Examiner's thorough examination of the application and requests reexamination and reconsideration of the application in view of the preceding amendments and the following remarks.

As a preliminary matter, the applicants are submitting formal drawings corresponding to the previously filed drawings which have been accepted by the Examiner. No new matter is added.

THE REJECTIONS BASED ON 35 U.S.C. §101

The Examiner rejects claims 1-43, 50 and 51 under 35 U.S.C. 101, taking the position that the invention claimed is directed to non-statutory subject matter.

Claims 1-45 have been cancelled. Claim 50 has been amended to recite, *inter alia*, a method of using a processor for obtaining information about a subject, providing magnetic property values from a scanner, and labeling of tissue types by the processor. Thus, amended claim 50 clearly is directed to statutory subject matter, namely a new process which is not merely a compilation of data. No new matter has been added. See e.g. the applicants' Fig. 12 and the specification at page 19, lines 14-18.

With respect to the new claims for an atlas, the claims recite that the atlas is implemented in software, and thus are directed to statutory subject matter.

[A] claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory.

See MPEP §2106 IV.B.1.(a).

No new matter has been added, as one of ordinary skill in the art would recognize that atlases similar to those claimed by the applicants -- although not new or unique in contrast to the applicants' claimed atlas -- are implemented in software.

Moreover, the applicants' claimed atlas has specific uses which would be recognized by those skilled in the art, i.e. magnetic resonance image applications. In contrast to typical atlases as typically comprised, with the applicants' claimed atlas the overall probability of correctly assigning a tissue classification, i.e. brain gray matter, white matter, or cerebral spinal fluid, to a point within the scanned subject is greatly improved. Also, for example, the applicants' claimed invention may be used with a non-landmark based neuro-alignment application. When integrated into MR console workflow, it allows MRI technologists to generate consistent patient image registrations for image acquisition. This offers improvement over typical manual processes of image registration. Another application is the assignment of a structural label (i.e. left and right hippocampus, left and right lateral ventricle) of each voxel (or percentage of voxels) in a given acquired MRI-multi-spectral volume. This application is useful for accurately and reproducibly determining the volume of a given structure for assessment of the relative volume of the structure as compared to a specific matched population for classification of a patient's disease status. The applicants' claimed invention also has other uses as would be recognized by those of ordinary skill in the art.

Accordingly, the applicants request that the Examiner withdraw the rejections based on 35 U.S.C. §101.

THE REJECTIONS BASED ON DECHARMS UNDER 35 U.S.C. §102(e)

The Examiner also rejects claims 1-7 and 13-68 under 35 U.S.C. §102(e) as being

anticipated by U.S. Patent Application Publication No. 2002/0103428 to *deCharms*, and rejects claims 8, 11 and 12 under 35 U.S.C. §103(a) as being unpatentable over *deCharms* in view of U.S. Pat. No. 6,845,342 to *Basser et al.*

deCharms describes regions or volumes of interest as referring to one or more voxels of the brain of a subject [0160], and that a scan volume may be divided into an array of voxels [0164]. A spatial activity pattern may be a three-dimensional array of voxels [0167], and it may allow the geometric points in the brain of one subject to be aligned with anatomically or physiologically corresponding points in another subject or group of subjects [0167]. *deCharms* further teaches the use of brain scanning technology such as MRI/fMRI [0188], and that T1 and/or T2 weighted anatomical image data collected from axial slices through the head which will be in substantial register with physiological data collected later [0264] (or use of T2*-sensitive gradient echo-spiral pulse sequence [0270]). An embodiment collects axial slices, with each slice having a given voxel resolution to produce a specified voxel brain volume data [0264]. *deCharms* utilizes atlases as a reference with respect to collected anatomical information to measure positions relative to brain landmarks. See e.g. [326], [0609]

In contrast to the applicants' claimed invention, however, *deCharms* only teaches the use of known standard atlases.

For example, *deCharms* does not disclose an atlas comprised of a plurality of nodes corresponding to a plurality of voxels, each of the nodes configured to store at least two magnetic property values for each of the voxels (see e.g. the applicants' independent claim 69). In fact, *deCharms* gives the example of measuring (only) T2* activation. See e.g. [0377], [0459]. Moreover, *deCharms* admits that “[a] single T2* weighted image by itself gives little information about the activity level at each voxel position...” [0459]

In other words, *deCharms* fails to disclose teach or suggest a multi-spectral atlas wherein each voxel has more than one corresponding magnetic property value. As noted above, the use of a multi-spectral atlas as claimed instead of using a single magnetic property alone provides greatly improved accuracy.

Similarly, a multi-spectral atlas is also claimed in the applicants' independent claim 77 which recites, *inter alia*, an atlas comprising a plurality of nodes corresponding to a plurality of voxels, each of the nodes configured to store at least one magnetic property value and at least one tissue type prior probability value corresponding to a tissue type of a voxel. *deCharms* fails to disclose teach or suggest an atlas with more than one value for each voxel. Also, in further contrast to this claim, *deCharms* fails to disclose, teach or suggest tissue type prior probability corresponding to a tissue type.

The applicants' independent claims 78, 81, and 88 each recite an atlas with various multi-spectral values, and the multi-spectral values claimed in each are such that none is anticipated or obvious over *deCharms*, for at least the same reasons as claims 69 and 77 discussed above. Independent claim 92 is for a system which includes an atlas with multi-spectral values, as discussed previously.

Accordingly, independent claims 69, 77, 78, 81, 88 and 92 are not anticipated by *deCharms* and thus are in condition for allowance. Claims 70-76 depend directly or indirectly from claim 69; claims 79 and 80 depend directly or indirectly from claim 78; claims 82-87 depend directly or indirectly from claim 81; and claims 89-91 depend directly or indirectly from claim 88. Accordingly, these claims are also in condition for allowance for at least the foregoing reasons.

The applicants' amended independent claim 46 recites a method for obtaining

information about a subject which includes providing an atlas having magnetic resonance image data including tissue type prior probability derived from at least one other subject. As noted above, *deCharms* does not disclose tissue type prior probability at all. Accordingly, claim 46 is in condition for allowance, as are claims 47-48 which depend from claim 46. Also, new claim 93 includes an atlas having magnetic resonance data including more than one magnetic property value prior probability derived from at least one other subject, also not disclosed by *deCharms*. Accordingly, claim 93 and dependent claims 94 and 95, are also in condition for allowance.

The applicants' amended independent claim 50 recites a method of using a processor for obtaining information about a subject, which includes providing an atlas having at least two magnetic property values for at least one corresponding voxel derived from at least one other subject. *deCharms* fails to disclose such an atlas, as discussed in detail above. Accordingly, claim 50 is in condition for allowance, as is claim 51 which depends from claim 50.

The applicants' independent claims 52 and 57 each recite a method for creating an atlas. In contrast, *deCharms* does not disclose a method for creating an atlas, but instead discloses use of known atlases, i.e. for reference. Moreover, in contrast to the applicants' claims 52 and 57, *deCharms* fails to disclose, *inter alia*, correcting distortion of magnetic resonance modality volumes prior to recording (or updating) a magnetic property value in node of the atlas. *deCharms* discloses pre-processing, i.e. removal of noise in the data via a 2-D or 3-D gaussian filter [0439] or lowpass, highpass or bandpass filters [0441], but it has no relationship to storing magnetic property values in the node of an atlas.

Accordingly, *deCharms* does not anticipate claims 52 and 57. Claim 53 has been cancelled. Claims 54-56 depend from claim 52. Claim 58 depends from claim 57. Accordingly, claims 54-56 and 58 are also in condition for allowance for at least these reasons.

Finally, the applicants note that the goal of *deCharms* is to treat conditions that have a cause directly related to an inappropriate level or pattern of neural activation within a discretely localized brain region, using technology that allows these discretely localized brain regions to be directly spatially targeted, controlled, trained and exercised [0195].

In order to find invalidity based on anticipation, not only must all of the elements of all the claims be found within a single prior art reference, but “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art.” See e.g. Scripps Clinic v. Genentech, Inc., 927 F.2d 1565, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

A person of ordinary skill in the art would view a vast difference between a system and method for physiological monitoring, training, exercise and regulation which in some embodiments utilizes known atlases as disclosed by *deCharms*, and an atlas -- and/or methods for creating an atlas -- and the other systems and methods including the elements as claimed by the applicants.

CONCLUSION

Each of Examiner's rejections has been addressed or traversed. Accordingly, it is respectfully submitted that claims 46-48, 50-52, 54-58, and 69-95 are in condition for allowance. Early and favorable action is respectfully requested.

If for any reason this Response is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the

undersigned or his associates, collect in Waltham, Massachusetts at (781) 890-5678.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "T. Thompson". The signature is written in a cursive, slightly stylized font.

Thomas E. Thompson, Jr.
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